

117TH CONGRESS  
1ST SESSION

# H. R. 4711

To amend the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 to include principal negotiating objectives of the United States relating to trade in pharmaceutical products, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 27, 2021

Mr. JOYCE of Pennsylvania (for himself and Mr. BANKS) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Rules, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 to include principal negotiating objectives of the United States relating to trade in pharmaceutical products, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-  
2       tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “International Pharma-  
5       ceutical Supply Chain Security Agreement Act of 2021”.

1   **SEC. 2. PRINCIPAL NEGOTIATING OBJECTIVES OF THE**  
2                   **UNITED STATES RELATING TO TRADE IN**  
3                   **COVERED PHARMACEUTICAL PRODUCTS.**

4       Section 102(b) of the Bipartisan Congressional Trade  
5   Priorities and Accountability Act of 2015 (19 U.S.C.  
6   4201(b)) is amended by adding at the end the following:

7                  **“(23) TRADE IN COVERED PHARMACEUTICAL**  
8                  **PRODUCTS.—**

9                  “(A) IN GENERAL.—With respect to an  
10                 agreement relating to trade in covered pharma-  
11                 ceutical products that is proposed to be entered  
12                 into with the United States and to which sec-  
13                 tion 103(b) will apply, the principal negotiating  
14                 objectives of the United States are the fol-  
15                 lowing:

16                  “(i) To ensure that a party to the  
17                 agreement adopts and maintains measures  
18                 to eliminate the imposition or reimposition  
19                 of tariffs on imports of such products, par-  
20                 ticularly in the event of a declared emer-  
21                 gency.

22                  “(ii) To ensure that a party to the  
23                 agreement—

24                  “(I) will reduce or eliminate reg-  
25                 ulatory and other technical barriers in  
26                 the pharmaceutical sector;

1                         “(II) will promote expedited ap-  
2                         proval of facilities for the production  
3                         of such products being built by busi-  
4                         ness enterprises that operate one or  
5                         more such facilities in the territory of  
6                         the party;

7                         “(III) will promote the use of  
8                         good regulatory practices and stream-  
9                         lined regulatory review and approval  
10                         processes for the production of such  
11                         products in the territory of the party;

12                         “(IV) will eliminate duplicated  
13                         actions and other barriers to reduce  
14                         the time for approvals of both facili-  
15                         ties and such products; and

16                         “(V) will expand transparency  
17                         and cooperation with other parties  
18                         and their manufacturers, working col-  
19                         laboratively, to ensure regulatory  
20                         processes are streamlined and har-  
21                         monized among other parties to the  
22                         maximum extent possible.

23                         “(iii) To prohibit export restraints  
24                         against parties to the agreement, particu-  
25                         larly in the event of a declared emergency.

1                     “(iv) With respect to use of sub-  
2                     sidies—

3                         “(I) to encourage the coordinated  
4                     provision of those types of subsidies  
5                     that are classified under World Trade  
6                     Organization rules as ‘non-prohibited’,  
7                     such as subsidies that are not contin-  
8                     gent on exports or import-substi-  
9                     tution, to incentivize manufacturing of  
10                    such products, including the provision  
11                    of grants, loans, tax incentives, and  
12                    guaranteed price and volume con-  
13                    tracts;

14                    “(II) to explicitly permit, among  
15                    parties to the agreement, the use of  
16                    production subsidies to build pharma-  
17                    ceutical manufacturing capacity;

18                    “(III) to affirm that subsidies  
19                    provided by parties are not intended  
20                    to be used primarily for export or to  
21                    distort trade;

22                    “(IV) to affirm parties’ commit-  
23                    ments under the Antidumping Agree-  
24                    ment and the Agreement on Subsidies  
25                    and Countervailing Measures, includ-

“(V) to encourage notification and consultation among parties as they are considering pharmaceutical manufacturing subsidies to increase coordination and avoid creating conditions such as oversupply or market inefficiencies among the parties.

18                             “(v) With respect to government pro-  
19                             curement—

“(II) to increase coordination between participant countries and facilitate the involvement of participant

1                   countries' companies in bids to supply  
2                   such products; and

3                   “(III) to ensure that any partici-  
4                   pant in the agreement that is not al-  
5                   ready so designated, becomes des-  
6                   gnated for purposes of section 301 of  
7                   the Trade Agreements Act of 1979  
8                   (19 U.S.C. 2511).

9                   “(vi) With respect to trade in serv-  
10                  ices—

11                  “(I) to obtain fair, open, and  
12                  transparent access to supply chain  
13                  services in the markets of parties to  
14                  the agreement, such as distribution,  
15                  logistics, and transportation services;

16                  “(II) to ensure any restrictions  
17                  or regulatory requirements maintained  
18                  on such services are adopted and  
19                  maintained in a transparent and effi-  
20                  cient manner; and

21                  “(III) to require parties to estab-  
22                  lish an internal process for identifying  
23                  restrictions or regulatory require-  
24                  ments that could be waived in the  
25                  event of a declared emergency.

1                     “(vii) With respect to transparency  
2                     and trade facilitation—

3                         “(I) to obtain commitments  
4                     among parties to the agreement to de-  
5                     velop mechanisms for sharing infor-  
6                     mation on pharmaceutical supply  
7                     chain constraints and coordinate ap-  
8                     proaches with parties to minimize  
9                     risks that could lead to supply chain  
10                    failures; and

11                    “(II) to the extent they have not  
12                    done so yet, to obtain commitments  
13                    from parties that they will fully imple-  
14                    ment the obligations under the World  
15                    Trade Organization’s Agreement on  
16                    Trade Facilitation prior to the date  
17                    the agreement enters into force.

18                    “(viii) With respect to enforcement—

19                         “(I) to ensure that benefits under  
20                     the agreement can only be obtained by  
21                     parties that are fully meeting their ob-  
22                     ligations under the agreement;

23                         “(II) to ensure that parties will  
24                     not bring a dispute under another

1                   agreement for actions that are con-  
2                   sistent with the agreement; and

3                   “(III) to provide a dispute settle-  
4                   ment mechanism comparable to the  
5                   dispute settlement provisions of the  
6                   Agreement between the United States  
7                   of America, the United Mexican  
8                   States, and Canada.

9                   “(ix) To minimize the ability of par-  
10                  ties to the agreement to undermine the ef-  
11                  fectiveness of the agreement by abusing ex-  
12                  ceptions in the agreement by including ad-  
13                  ditional procedural requirements, such as  
14                  notification of intent to rely on an excep-  
15                  tion at the time an inconsistent action is  
16                  taken, and limiting the duration that par-  
17                  ticipants may rely on an exception.

18                  “(B) DEFINITIONS.—In this paragraph:

19                  “(i) ACTIVE PHARMACEUTICAL INGRE-  
20                  DIENT.—The term ‘active pharmaceutical  
21                  ingredient’—

22                  “(I) means any component that  
23                  is intended to furnish pharmacological  
24                  activity or other direct effect in the  
25                  diagnosis, cure, mitigation, treatment,

1                   or prevention of a disease, or to affect  
2                   the structure or any function of the  
3                   body of a human or animal; and

4                   “(II) does not include—

5                   “(aa) intermediates used in  
6                   the synthesis of a drug product;  
7                   or

8                   “(bb) components that may  
9                   undergo chemical change in the  
10                  manufacture of a drug product  
11                  and be present in a drug product  
12                  in a modified form that is in-  
13                  tended to furnish such activity or  
14                  effect.

15                  “(ii) AGREEMENT ON SUBSIDIES AND  
16                  COUNTERVAILING MEASURES.—The term  
17                  ‘Agreement on Subsidies and Counter-  
18                  vailing Measures’ means the agreement re-  
19                  ferred to in section 101(d)(12) of the Uru-  
20                  guay Round Agreements Act (19 U.S.C.  
21                  3511(d)(12)).

22                  “(iii) ANTIDUMPING AGREEMENT.—  
23                  The term ‘Antidumping Agreement’ means  
24                  the Agreement on Implementation of Arti-  
25                  cle VI of the General Agreement on Tariffs

1                   and Trade 1994 referred to in section  
2                   101(d)(7) of the Uruguay Round Agree-  
3                   ments Act (19 U.S.C. 3511(d)(7)).

4                   “(iv) BIOLOGICAL PRODUCT.—The  
5                   term ‘biological product’ has the meaning  
6                   given to such term in section 351(i) of the  
7                   Public Health Service Act (42 U.S.C.  
8                   262(i)).

9                   “(v) COVERED PHARMACEUTICAL  
10                  PRODUCT.—The term ‘covered pharma-  
11                  ceutical product’ means—

12                  “(I) a drug (including a biologi-  
13                  cal product); or  
14                  “(II) an active pharmaceutical  
15                  ingredient.”.

16 **SEC. 3. REAUTHORIZATION OF TRADE AGREEMENTS AU-**  
17 **THORITY.**

18                  Section 103 of the Bipartisan Congressional Trade  
19                  Priorities and Accountability Act of 2015 (19 U.S.C.  
20                  4202) is amended—

21                  (1) in subsection (a)—  
22                   (A) by striking “July 1, 2018” each place  
23                   it appears and inserting “July 1, 2023”; and  
24                   (B) by striking “July 1, 2021” each place  
25                   it appears and inserting “July 1, 2026”;

- 1                     (2) in subsection (b)—  
2                         (A) by striking “July 1, 2018” each place  
3                         it appears and inserting “July 1, 2023”; and  
4                         (B) by striking “July 1, 2021” each place  
5                         it appears and inserting “July 1, 2026”; and  
6                     (3) in subsection (c)—  
7                         (A) by striking “July 1, 2018” each place  
8                         it appears and inserting “July 1, 2023”;  
9                         (B) by striking “June 30, 2018” and in-  
10                         serting “June 30, 2023”;  
11                         (C) in paragraph (1)(B), by striking “July  
12                         1, 2021” and inserting “July 1, 2026”;  
13                         (D) in paragraph (2), by striking “April 1,  
14                         2018” and inserting “April 1, 2023”; and  
15                         (E) in paragraph (3), by striking “June 1,  
16                         2018” and inserting “June 1, 2023”.

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